

PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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NOTIFICATION OF TRANSMITTAL OF  
INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT

(PCT Rule 71.1)

Applicant's or agent's file reference  088/03504	Date of Mailing (day/month/year)  23 FEB 2005	
<b>IMPORTANT NOTIFICATION</b>		
International application No.  PCT/IL03/00769	International filing date (day/month/year)  25 September 2003 (25.09.2003)	Priority date (day/month/year)  25 September 2002 (25.09.2002)
Applicant  BY-PASS, INC.		

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US  Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer  Bradford C. Pantuck Telephone No. (703) 308-0858
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Form PCT/IPEA/416 (July 1992)

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PATENT COOPERATION TREATY

**PCT**

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 088/03504	FOR FURTHER ACTION      See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IL03/00769	International filing date (day/month/year) 25 September 2003 (25.09.2003)	Priority date (day/month/year) 25 September 2002 (25.09.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61B 17/08 and US Cl.: 606/153		
Applicant BY-PASS, INC.		

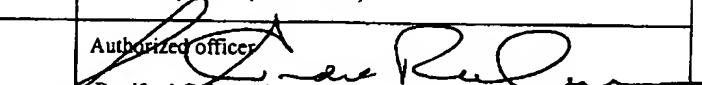
1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

- I  Basis of the report
- II  Priority
- III  Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV  Lack of unity of invention
- V  Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI  Certain documents cited
- VII  Certain defects in the international application
- VIII  Certain observations on the international application

Date of submission of the demand 22 April 2004 (22.04.2004)	Date of completion of this report 04 January 2005 (04.01.2005)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer  Bradford C Pantuck Telephone No. (703) 308-0858

Form PCT/IPEA/409 (cover sheet)(July 1998)

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/IL03/00769

**I. Basis of the report****1. With regard to the elements of the international application:\*** the international application as originally filed. the description:

pages 1-31 as originally filed

pages NONE, filed with the demandpages NONE, filed with the letter of \_\_\_\_\_ the claims:

pages 32, 34-37, 39 as originally filed

pages NONE, as amended (together with any statement) under Article 19

pages 33, 38, filed with the demand

pages NONE, filed with the letter of \_\_\_\_\_ the drawings:

pages 1-23 as originally filed

pages NONE, filed with the demandpages NONE, filed with the letter of \_\_\_\_\_ the sequence listing part of the description:pages NONE, as originally filedpages NONE, filed with the demandpages NONE, filed with the letter of \_\_\_\_\_**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

 the language of a translation furnished for the purposes of international search (under Rule 23.1(b)). the language of publication of the international application (under Rule 48.3(b)). the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:** contained in the international application in printed form. filed together with the international application in computer readable form. furnished subsequently to this Authority in written form. furnished subsequently to this Authority in computer readable form. The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.**4.  The amendments have resulted in the cancellation of:** the description, pages NONE the claims, Nos. NONE the drawings, sheets/fig NONE**5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/IL03/00769

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. STATEMENT**

Novelty (N)	Claims <u>8, 11, 16-23, 26-30, 32-57</u>	YES
	Claims <u>1-7, 9, 10, 12-15, 24, 25, 31</u>	NO
Inventive Step (IS)	Claims <u>8, 11, 16-23, 26-30, 32-48, 50-57</u>	YES
	Claims <u>1-7, 9, 10, 12-15, 24, 25, 31, 49</u>	NO
Industrial Applicability (IA)	Claims <u>1-57</u>	YES
	Claims <u>NONE</u>	NO

**2. CITATIONS AND EXPLANATIONS**

Claims 1-7, 9, and 10 lack novelty under PCT Article 33(2) as being anticipated by Publication No. US 2002/0099394 A1 to Houser et al. Regarding Claims 1-3, 6, 7, and 9 Houser discloses in Figures 53a and 53b and in Paragraph [0176] a plurality of leg confiniers (four radially extendable protrusions at the distal end of 440) having slots (442) between them. Houser also discloses a coupler (34), which couples a graft to the leg confiniers (see para. [0176]). The *leg confiniers are configured to move in an inner direction* ["the fittings are compressible into a low profile for insertion into a vessel"], particularly when "splittable tubing (not shown)" is slid over the leg confiniers {see para. [0176]}. This splittable tubing is a control for splitting at least a portion of the system. Various spacing distances can be maintained between the confiniers and a graft vessel.

Regarding Claim 4, the leg confiniers are shaped in a circle.

Regarding Claim 5, the configuration is used for an end-to-side anastomosis procedure, so a graft is certainly a part of the procedure.

Regarding Claim 10, each confiner is capable of receiving a single leg.

Claims 12-15, 24, 25, and 31 lack novelty under PCT Article 33(2) as being anticipated by Publication No. US 2002/0022852 A1 to Dakov. Dakov discloses a system that, although not intended for the purpose outlined by Applicant is certainly capable of such an intended use. Dakov discloses a coupler (313) at the proximal end and two elongated leg confiniers (306), which move in an inward direction [see Figures 26A and 26B]. Dakov's instrument has all of the claimed structure of Applicant's invention.

Regarding Claim 31 Dakov's instrument had a body (312) capable of receiving a connector, a handle (the user can grasp the instrument at its proximal end), and by rotating the elongated arms (306) the user has control over the mechanism.

Claim 49 lacks an inventive step under PCT Article 33(3) as being obvious over Publication No. US 2002/0099394 A1 to Houser et al. It would be obvious to put Houser's arrangement including a plurality of leg segments (440) and band (34) in a sterile package as is well-known in the medical art.

Claims 8, 11, 16-23, 26-30, 32-48, and 50-57 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the claimed inventions.

Claims 1-57 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

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VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted: